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Applicant(s): Edward W. MERRILL *et al.*

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Title: RADIATION AND MELT TREATED ULTRA HIGH MOLECULAR
WEIGHT POLYETHYLENE PROSTHETIC DEVICES

Commissioner for Patents
U.S. Patent and Trademark Office
PO Box 1450
Alexandria, Virginia 22331-1450

DECLARATION OF ORHUN K. MURATOGLU

I, Orhun K. Muratoglu, do hereby declare as follows:

1. I received my Ph.D. in Materials Science and Engineering, Program in Polymer Science and Technology, from the Massachusetts Institute of Technology ("MIT") in 1995. I have been engaged in the study of polymers, such as ultra high molecular weight polyethylene (UHMWPE), for use in medical implants for over 12 years. I have authored or co-authored at least 45 peer-reviewed articles and 14 book chapters and review articles concerning cross-linked and wear resistant UHMWPE and methods of making such UHMWPE for medical implants. I am currently the co-director of the Harris-Orthopedic Biomechanics and Biomaterials Laboratory at the Massachusetts General Hospital. A copy of my *curriculum vitae* is attached at tab 1.

2. I understand that the claims in the captioned patent application have been rejected under various grounds for enablement, and anticipation/obviousness rejections in view of Salovey *et al.* (6,281,264), Shen *et al.* (6,228,900), and Hyon *et al.* (6,168,626). I am not an inventor of the subject matter claiming the captioned application.

3. The claimed product is obtainable by a process as recited in claim 150, 167, or 174, which requires steps that include: (a) irradiation of the polyethylene; (b) ceasing of

irradiation of the polyethylene, which is at a temperature above the room temperature; (c) repeating steps (a) and (b) at least once to obtain a total absorbed radiation dose of about 5 to about 100 MRad; and (d) allowing the cross-linked polyethylene to cool.

4. It is my understanding that applicants submitted a declaration (Rule 1.131 declaration, filed on July 16, 2004 in a related application US Serial No. 10/197,263, filed July 18, 2002, a copy of which was re-submitted with the response filed on July 27, 2007) showing the invention before the priority dates of the cited references (that is, prior to January 20, 1995), and that the process steps as recited in the claims are supported by the original specification. Apparently, the examiner could not determine whether the process steps such as the "pause" or "cease" in-between the passes or irradiations, cooling during the pause, and at the end of the process is clear to one skilled in the art in order to be able to say that the claims are enabling.

5. I have reviewed the Rule 1.131 declaration and found that Exhibit 3 of the declaration clearly shows the Experiment 2 described step by step process of irradiation, pause or cease in-between the passes, heating the consolidated polymer in-between the steps (that maintains a temperature above the room temperature), and continued irradiation until a total dose of up to 50 Mrads was attained (see below, as reproduced from the Exhibit 3):

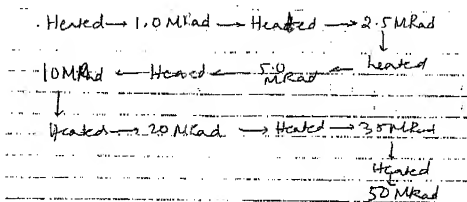
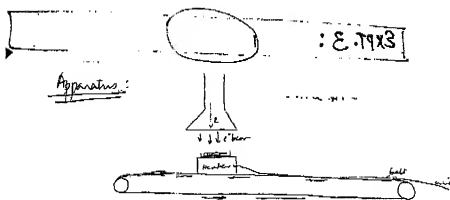


Exhibit 3 of the declaration also depicts a sketch of the van de Graaff generator as the radiation source and a consolidated polymer on the conveyer belt passing under the radiation source (see below for the sketch as shown in Experiment 4, source: Exhibit 3 of the declaration):



This depiction shows the irradiation step using van de Graaff generator in the Experiment 4. The sample receives no radiation dose when it is outside of the e-beam radiation station and continues to move on the conveyer belt until it is put back on the belt for a second dose. The process is repeated to obtain a total dose of 5 Mrad or more, because the van de Graaff generator provides a dose of 2.5 Mrad per pass per pass in this experiment. The van de Graaff generator can also be adjusted to deliver higher or lower radiation doses per pass.

It is clear to the skilled persons and lay persons alike from the above sketch that there is a pause or the radiation ceases when sample passes out of the radiation zone and the steps of radiation and ceasing radiation are repeated until the desired total dose is received by the sample.

6. I also have reviewed the 08/600,744 patent application, as filed on February 13, 1996, which discloses a process for preparing a medical implant by (a) irradiating polymeric material, (b) ceasing radiation while the temperature of the polymer is above room temperature, (c) repeating the steps (a) and (b), and (d) cooling the radiation cross-linked material. The process, as disclosed in Example 6 on pages 44-46 (of the 08/600,744 specification), shows that the polymeric material was above the room temperature throughout the irradiation process of cross-linking, including between two or after each dose of irradiation, that is, when the irradiation was ceased.

7. The instant specification also discloses that radiation doses are applied in sequential steps or passes, and subsequently the consolidated cross-linked polyethylene is allowed to cool. Example 8 of the specification describes consolidated polyethylene (pucks) are treated with sequential steps or repeated passes of irradiation at a dose rate of

2.5 Mrad per pass to 2.5, 5, 7.5, 10, 12.5, 15, 17.5, 20, 30, and 50 Mrad total absorbed dose. That is, for a total absorbed dose of 5, 7.5, 10, 12.5, 15, 17.5, 20, 30, and 50, the radiation step is repeated for 2, 3, 4, 5, 6, 7, 8, 12, etc., respectively. Clearly, the specification teaches sequential steps or passes (see Example 8 of the specification), heating and cooling after irradiation (see Examples 6 and 8 of the specification). Thus, it is obvious to one skilled in the art that the invention provides methods of repeated steps of irradiation, heating, and cooling of the cross-linked consolidated polyethylene.

8. It is also clear from the specification that, for example, for a total dose of 5-20 Mrad at the dose rate of 2.5 Mrad per pass, it takes at least two passes of irradiation while the polyethylene is maintained at a temperature above the room temperature and the irradiation is ceased in between two or after each dose of irradiation (see for example, Example 9 at pages 48-49). In other words, such "pause" or "cease" in-between the passes or irradiations and repeating of the steps were necessary at the time to complete the process in order to obtain a desired total dose of 5-20 Mrad at the dose rate of 2.5 Mrad per pass. Because, the van de Graaff generator used at the time generated a dose rate of 2.5 Mrad per pass (see specification, for example, page 33, 41, and 45). Thus, the original specification (as filed on February 13, 1996) teaches steps of "ceasing irradiation between irradiation steps", as the person skilled in the art would immediately appreciate. Further, it is apparent from the Rule 1.131 declaration, that the steps shown under Experiment 2 and the sketch of the radiation using van de Graaff generator shown at Experiment 4 (see above) made the process clear to one skilled in the art. Therefore, the polymeric material prepared according to the methods disclosed in the original specification involved the steps of: (a) irradiating the polymeric material; (b) ceasing irradiation while the temperature of the polymer is above room temperature; (c) repeating the steps (a) and (b); and (d) cooling the radiation cross-linked material.

9. I declare further that all statements made herein of my own knowledge are true and that all statements made or information and belief are believed to be true; and further that these statements and the like are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001

of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

7/15/08

Date



Orhun K. Muratoglu, Ph. D.

CURRICULUM VITAE

DATE PREPARED: July 16, 2008

Name: Orhun K. Muratoglu

Home Address: 5 Dana St
Cambridge, MA 02138 United States

Office Address: Massachusetts General Hospital
Orthopaedic Biomechanics and Biomaterials Laboratory
55 Fruit St. GRJ 1206
Boston, MA 02114 United States

Phone: (617) 726-3869

Email: omuratoglu@partners.org

Fax: (617) 726-3883

Place of Birth: Erzurum, Turkey

Education:

1991 B.S. (Materials Science and Engineering), Rensselaer Polytechnic Institute of Technology
1995 Ph.D. (Materials Science and Engineering, Program in Polymer Science and Technology), Massachusetts Institute of Technology

Academic Appointments:

1995- Research Affiliate, Massachusetts Institute of Technology, Cambridge, MA
1995-2002 Instructor in Orthopedic Surgery, Harvard Medical – Orthopedic Surgery, Boston, MA
2002-2005 Assistant Professor of Orthopedic Surgery, Harvard Medical School – Orthopedic Surgery, Boston, MA
2005- Associate Professor of Orthopedic Surgery, Harvard Medical School – Orthopaedic Surgery, Boston, MA

Hospital or Affiliated Institution Appointments:

1995-2002 Assistant Bioengineer, Orthopaedic Surgery, Massachusetts General Hospital, Boston, MA
1995-2002 Research Affiliate, Department of Chemical Engineering, Massachusetts Institute of Technology, Cambridge, MA
2001-2004 Deputy Director, Orthopedic Biomechanics and Biomaterials Laboratory, Massachusetts General Hospital, Boston, MA
2001- Alan Gerry Scholar, Massachusetts General Hospital, Boston, MA
2004- Co-Director, Orthopedic Biomechanics and Biomaterials Laboratory, Massachusetts General Hospital, Boston, MA

Professional Societies:

1990-	Materials Research Society, Member
1990-	American Chemical Society, Member
1995-	American Institute of Chemical Engineers, Member
1995-	Society for Biomaterials, Member
1996-	American Society for Testing and Materials, Member
1997-	Orthopaedic Research Society, Member
2000-	American Academy of Orthopaedic Surgeons, Member
2003-	American Academy of Hip and Knee Surgeons, Member

Editorial Boards:

1997-	Ad-Hoc Reviewer, Clinical Orthopaedic and Related Research
1997-	Ad-Hoc Reviewer, Journal of Biomedical Materials Research
1997-	Ad-Hoc Reviewer, Biomaterials
2001	Ad-Hoc Reviewer, Austrian Science Fund
2003-	Ad-Hoc Reviewer, Journal of Orthopaedic Research
2005-	Ad-Hoc Reviewer, Polymer
2006-	Ad-Hoc Reviewer, US-Israel Bi-national Science Foundation (BSF)

Awards and Honors:

1989-1990	Dean's List, Rensselaer Polytechnic Institute
1991	Summa cum Laude, Rensselaer Polytechnic Institute
1991	PPST Fellowship, Massachusetts Institute of Technology
1991	Matthew Albert Hunter Prize for Outstanding Academic Achievement, Rensselaer Polytechnic Institute
1992	Dupont Fellowship, Massachusetts Institute of Technology
1995	First Prize, Hoechst Celanese Polymer Poster Competition, Massachusetts Institute of Technology
1995	Summa cum Laude, Massachusetts Institute of Technology
1998	Best Paper Award, Montreal RETEC '97 Society of Plastics Engineers
1999	HAP Paul Award, International Society for Technology in Arthroplasty
2000	Partners in Excellence Award, Massachusetts General Hospital
2001	Marshall R. Urist Young Investigator Award, American Academy of Orthopaedic Surgeons
2006	HAP Paul Award, International Society for Technology in Arthroplasty

a. Invited Presentations

Invited Lectures

International Invited Lectures

2000	Invited Lecture: Highly crosslinked polyethylene in total joints at the 27th Annual Meeting, Japanese Hip Society, Nagoya, Japan
2000	Invited Lecture: European Knee Osteoarthritis Week, Arthroplasty Symposium, University of Ulm, Germany
2000	Invited Lecture: Irradiated and melted UHMWPE tibial knee inserts at the 85th National Congress, Torino, Italy, Italian Society of Orthopaedics and Traumatology

- 2000 Invited Lecture: Radiation crosslinked UHMWPE for total knees at the 2nd Harlaching Spring Symposium, Academic Hosp Munchen-Harlaching, Munich, Germany
- 2000 Invited Lecture: Residual free radicals in UHMWPE. Whistler 2000 Orthopaedic Symposium, Whistler, British Columbia, Zimmer
- 2001 Invited Lecture: Highly crosslinked polyethylenes in total joints at the Osteologie in Forschung und Praxis -Der Osteoblast, University of Wurzburg, Wurzburg, Germany
- 2001 Invited Lecture: In vitro testing of highly crosslinked total knees at the Triennial Congress, Asian Pacific Orthopaedic Association, Adelaide, South Australia
- 2002 Invited Lecture: Radiation chemistry in improving wear and oxidation resistance of UHMWPE - 3rd Annual Turkish Arthroplasty Meeting, The Association of Turkish Arthroplasty Surgeons, Antalya, Turkey
- 2003 Invited Lecture: The effect of third body particles on in vivo wear of crosslinked acetabular liners at the Satellite Symposium, European Orthopaedic Research Society, Helsinki, Finland
- 2003 Invited Lecture: The state-of-the-art of crosslinked UHMWPEs in orthopedics at the Annual Meeting, European Federation of National Associations of Orthopaedic and Traumatology, Helsinki, Finland
- 2004 Invited Lecture: Limitations of contemporary crosslinked polyethylenes and potential 2nd generation solutions, Peter Herberts Festschrift, Sahlgrenska University Hospital, Goteborg, Sweden
- 2004 Invited Lecture: Materials Science in Orthopaedics: Low-Wear, High Fatigue Polyethylenes for Total Joints, Biomed Meeting, Ankara, Turkey
- 2005 Invited Lecture: The effect of alpha-tocopherol on the wear of radiation crosslinked UHMWPE, Oxidative Stabilization of UHMWPE, Turin, Italy
- 2005 Invited Lecture: Alpha-tocopherol stabilized irradiated acetabular liners, UHMWPE for arthroplasty: degradation, stabilization and crosslinking, Turin, Italy
- 2005 Invited Lecture: Second Generation Highly Crosslinked UHMWPE for Total Joint Arthroplasty, SICOT, Istanbul, Turkey
- 2006 Invited Lecture: Radiation Chemistry of Polyethylenes for Total Joint Application, IRaP, Antalya, Turkey
- 2006 Invited Lecture: Presidential Guest Lecturer: New Horizons in Polyethylene Technology, European Hip Society, Antalya, Turkey

National Invited Lectures

- 1995 Invited Lecture: The effects of gamma sterilization on UHMWPE. Workshop on Polyethylene, Combined Orthopaedic Research Society
- 1998 Invited Lecture: The effect of crosslinking on wear at the Material Science and Engineering Colloquium Series, Ohio State University
- 1999 Invited Lecture: Seminar Series at the Mechanical Engineering, Aeronautical Engineering and Mechanics, Rensselaer Polytechnic Institute
- 1999 Invited Lecture: Hip simulator wear studies at the Hip, Knee, and Shoulder Symposium, University of Florida

- 2000 Invited Lecture: High cycle wear testing of highly crosslinked UHMWPE acetabular liners at the Hip, Knee, and Shoulder Symposium, University of Florida
- 2000 Invited Lecture: Wear 2000 Workshop, Orthopaedic Research Society
- 2000 Invited Lecture: Low wear and low oxidation with irradiated and melted UHMWPE at the Wear 2000 Workshop, American Academy of Orthopaedic Surgeons and National Institute of Health
- 2001 Invited Lecture: Workshop on Ultra-high molecular weight polyethylene , Society for Biomaterials
- 2001 Invited Lecture: New Test Methods for Evaluating the Performance of Conventional and Crosslinked UHMWPE , American Society for Testing and Materials
- 2001 Invited Lecture: Analysis of explanted highly crosslinked UHMWPE at the Tribology Issues in Biology and Medicine, Argonne National Laboratory
- 2002 Invited Lecture: Overview of radiation chemistry of UHMWPE for orthopedics at the Grand Rounds, University of Oklahoma College of Medicine
- 2002 Invited Lecture: Surface Analysis of Early Retrieved Acetabular Polyethylene Liners, American Society for Testing and Materials
- 2002 Invited Lecture: Overview of radiation chemistry of UHMWPE for orthopedics at the Grand Rounds, University of Utah
- 2002 Invited Lecture: Highly crosslinked polyethylenes in total hip and total knee at the Hip, Knee, and Shoulder Symposium, University of Florida
- 2002 Invited Lecture: Effect of Crosslinking on the Delamination and Adhesive Wear Behavior of Tibial Knee Inserts, The Knee Society Meeting, American Academy of Hip and Knee Surgeons
- 2003 Invited Lecture: Update on highly crosslinked polyethylenes in total hip and total knee at the Hip, Knee, and Shoulder Symposium, University of Florida
- 2003 Invited Lecture: E-beam crosslinked and melted polyethylene, Alternate bearing surfaces in total joint replacement, University of Pennsylvania Medical Center
- 2003 Invited Lecture: Highly crosslinked polyethylene in total knees: Another view, Alternate Bearing Surfaces in Total Joint Replacement, University of Pennsylvania Medical Center
- 2003 Invited Lecture: Highly crosslinked polyethylene in total knees: Another view, Alternate bearing surfaces in total joint replacement , University of Pennsylvania Medical Center
- 2003 Invited Lecture: E-beam crosslinked and melted polyethylene, Alternate bearing surfaces in total joint replacement, University of Pennsylvania Medical Center
- 2004 Invited Lecture: Update on highly crosslinked polyethylenes in total hip and total knee at the Hip, Knee, and Shoulder Symposium, University of Florida
- 2004 Invited Lecture: Radiation crosslinked and melting of polyethylene, Hip, Knee and Shoulder Symposium, University of Pennsylvania Medical Center
- 2004 Invited Lecture: Diminished Polyethylene wear using a highly crosslinked polyethylene, The Knee Society Meeting, American Academy of Hip and Knee Surgeons
- 2005 Invited Lecture: Vitamin E Stabilized, Irradiated UHMWPE for TKR, Advances in Hip and Knee Arthroplasty Meeting, Washington DC

- 2005 Keynote Presentation: Improving the Wear Resistance of Ultra-high Molecular Weight Polyethylene (UHMWPE), World Tribology Congress, Washington DC
- 2005 Invited Panel Discussion: Alternate Bearing Surfaces, 20th Annual Vail Orthopaedic Symposium, Vail, Colorado
- 2006 Invited Lecture: Crosslinked UHMWPE in Total Knees, ISTA Meeting, New York, NY
- 2007 Grand Rounds at Dartmouth: Second Generation Highly Crosslinked UHMWPEs, Hanover NH

Regional Invited Lectures

- 2002 Invited Lecture: Crosslinked polyethylenes at the Fall Meeting, New England Orthopaedic Society
- 2004 Invited Lecture: Second Generation Crosslinked Polyethylenes for Total Joints at the Traveling Fellow Program AOA Presentation, Massachusetts General Hospital
- 2004 Invited Lecture: Current and Future Crosslinked Polyethylenes, How Good are They?, American Orthopaedic Association
- 2005 Keynote Speaker: Crosslinked polyethylenes, Harvard Hip Course, Harvard Medical School
- 2006 Invited Lecture: Polyethylene: New Perspectives at the Traveling Fellow Program AOA Presentation, Massachusetts General Hospital
- 2006 Invited Lecture: Second Generation Polyethylene, Harvard Hip Course, Harvard Medical School.
- 2006 Invited Presentation: Cross-Linked Polyethylene for the Knee, Harvard Hip Course, Harvard Medical School.

Plenary Presentation

- 1998 Plenary Presentation: Effect of Crosslinking on Wear of Polyethylene, Gordon Conference on Tribology

Bibliography

Original Articles

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3. Muratoglu OK, Cohen RE, Argon AS, Weinberg M. Microstructural processes of fracture of rubber modified polyamides. *Polymer*. 1995; 36(25):4771.
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7. Muratoglu OK, Bragdon CR, O'Connor DO, Jasty M, Harris WH. A novel method of cross-linking ultra-high-molecular-weight polyethylene to improve wear, reduce oxidation, and retain mechanical properties. Recipient of the 1999 HAP Paul Award. *J Arthroplasty*. 2001;16(2):149-60.
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12. Muratoglu OK, Bragdon CR, O'Connor D, Perinchieff RS, Estok DM, Jasty M, Harris WH. Larger diameter femoral heads used in conjunction with a highly cross-linked ultra-high molecular weight polyethylene: a new concept. *J Arthroplasty*. 2001; 16(8 Suppl 1):24-30.
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36. Oral E, Christensen S, Wannomae KK, Malhi A, Muratoglu OK. Wear Resistance and Mechanical Properties of Highly Crosslinked UHMWPE Doped with Vitamin E. *J Arthroplasty*, 2006; 21(4): 580-591.
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39. Estok D, Burroughs B, Muratoglu OK, Harris WH. Comparison of Hip Simulator Wear of Two Different Highly Crosslinked UHMWPE Acetabular Components using both 32 and 38-mm Femoral Heads. *Journal of Arthroplasty*; in print.
40. Plank G, Estok D, Burroughs B, O'Connor D, Muratoglu OK, Harris WH. Contact Stress Assessment of Conventional and Highly Crosslinking UHMWPE Acetabular Liners with Finite Element Analysis and Pressure Sensitive Film. *Journal of Biomedical Materials Research*; 2007; 80B:1-10.
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44. Oral E, Muratoglu OK. Vitamin C Hinders Radiation Cross-linking in Aqueous Poly (Vinyl Alcohol) Solutions. *Nuclear Inst. and Methods in Physics Research*. 2007; **B-265**: 92-97.
45. Oral E, Muratoglu OK. Radiation Cross-linking in Ultra-high Molecular Weight Polyethylene for Orthopaedic Applications. *Nuclear Inst. and Methods in Physics Research*. 2007; **B-265**: 18-22.
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Proceedings of Meetings

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Reviews/Chapters/Editorials

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